

ENZYMATIC THERAPY

what Better feels like."

NIEGRATIVE THERAPEUTICS INC.

NF Formulas - PhytoPharmica

NF Formulas • PhytoPharmica

Tyler Encapsulations • Vitaline Formulas

ENZYMATIC THERAPY' & PHYTOPHARMICA'

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.83860 /F:303.382.046/7

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) B: 920.469.9099 F: 920.469.4418 (Phyto)

P2:17

September 21, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

001 13 1

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENT</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Acidophilus Pearls™	With an optimal balance of healthy bacteria in your intestines, you will likely see a decrease in unhealthy bacteria, which can cause that troublesome occasional gas, loose stools, and constipation.*	Proprietary Probiotic Blend Lacetobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Bv:

The state

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:

9/21/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer 975 0162

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ENZYMATIC THERAPY

Tyler Encapsulations & Vitaline Formulas

9755 SW Commerce Circle, Suite B2

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 * F: 503.582.0467

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PRODUCT NAME	<u>STATEMENT</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Acidophilus Pearls™	Clinical studies show that supporting healthy levels of microflora in the intestine can also support yeast levels in other areas of the body.*	Proprietary Probiotic Blend Lacetobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

gy: Referred

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9/21/05

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September 22, 2005

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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Acidophilus Pearls™	Probiotics play a role in the production of essential vitamins, such as vitamin B12, folate, and vitamin K. These nutrients support many functions in your body including metabolizing fats and proteins and supporting energy, healthy nerves, skin and hair. Healthy levels of beneficial probiotics can help support production of these key nutrients.*	Proprietary Probiotic Blend Lacetobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:

9/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer

Acidophilus Pearls 47e